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January 7, 2004

President George Bush
The White House
Washington, D.C. 20500

Mark B. McClellan, M.D., Ph.D.
Commissioner, Food and Drug Administration
5600 Fishers Lane
Parklawn Bldg., Room 14-71
Rockville, MD 20857

01-13-04P05:06 RCVD

Dear President Bush & Dr. McClellan,

The purpose of this correspondence is to express deep concern and to voice opposition to the Food and Drug Administration's consideration of a proposal to allow "morning-after" pills to be sold over-the-counter without a prescription. The harm from the specific drug in question, "Plan B," a levonorgestrel-only pill, would reap incalculable harm upon lives in our country.

Since this recommendation is not binding, I urge the FDA, to oppose approval of the over the counter use of the Plan B pill. I urge this for several reasons:

- The pill can have an abortifacient effect. Over-the-counter availability will lead to a greater assault on human life at its earliest stages, and evidence shows it will not reduce abortions at later stages.
- Many women who would be deeply concerned about any abortifacient effect are unaware of how this drug works. Over-the-counter availability without medical counseling risks violating their right to informed consent.
- Plan B's manufacturer says it should not be used routinely, but over-the-counter availability encourages just such use. This exposes women to the serious risks of birth control pills, without medical supervision.
- Plan B is associated with a heightened risk of ectopic pregnancy, a potentially fatal condition. The common side-effects of the "morning-after" pill (nausea and abdominal pain) are also the symptoms of an ectopic pregnancy and could therefore mask the presence of this potentially life-threatening condition.
- The potential for harm is especially grave in the case of minor girls. They (and the males sexually involved with them) will obtain the pills without ever seeing a physician or notifying parents.
- Over-the-counter availability of the pill would likely increase the pressure already being placed on pharmacies and pharmacists to violate their consciences.

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